MAIL STOP APPEAL BRIEF-PATENTS
Attorney Docket No. 27579U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

ROSCHER et al. Confirmation No.: 3799

Serial No: 10/589,871 Group Art Unit: 1627

Filed: August 18, 2006 Examiner: CHONG, Y.S.

For: **CICLESONIDE AND GLYCOPYRRONIUM COMBINATION**

APPEAL BRIEF

This is an appeal to the Board of Patent Appeals and Interferences from the decision of Examiner Yong Soo Chong, mailed January 5, 2010, finally rejecting claims 1, 4, 8-11 and 19. Appellants timely filed a Notice of Appeal and a Petition for a Three-Month Extension of Time on June 28, 2010, making this Appeal Brief due by August 28, 2011. Accordingly, a Petition for a Five-Month Extension of Time is filed herewith, making the deadline for filing the Appeal Brief January 28, 2011. As such, this paper is timely filed.

1. Table of Contents

2. The Real Party in Interest

The real party in interest in this appeal is NYCOMED GmbH.

3. Related Appeals and Interferences

Appellants are not aware of any other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

4. Status of Claims

The status of the claims is as follows upon filing of this Appeal Brief:

Claims cancelled: 2-3, 5-7 and 12-13

Claims withdrawn from consideration but not cancelled: 14-18

Claims pending: 1, 4, 8-11 and 14-19

Claims objected to: None

Claims allowed: None

Claims rejected: 1, 4, 8-11 and 19

The claims on appeal are 1, 4, 8-11 and 19.

5. Status of Amendments

Appellants filed a Preliminary Amendment on August 18, 2006, in which claims 1-19 were amended.

Claims 1-19 were subject to a restriction and/or election requirement on December 24, 2008. Appellants elected claims 1-13 and 19 of Group I in their Response dated January 21, 2009.

Claims 14-18 were withdrawn by the Examiner in the Official Action mailed April 3, 2009. Appellants filed a Response and Amendment on September 3, 2009, in which claims 2, 3, 5-7 and 12-13 were canceled and claims 1, 4, 9 and 19 were amended.

The Examiner issued a final Official Action dated January 5, 2010 in which the rejections of record were maintained. A Notice of Appeal and a Petition for a Three Month Extension of Time were timely filed on June 28, 2010.

No further amendments have been made to the claims.

As such, Appellants submit that claims 1, 4, 8-11 and 19 are the currently pending claims on appeal. The claims listed in the Claims Appendix herein incorporate the claim amendments of the aforementioned Response and Amendment.

6. Summary of Claimed Subject Matter

Pending independent claim 1 claims a pharmaceutical formulation consisting of a pharmaceutical acceptable salt of glycopyrronium in combination with ciclesonide, and lactose monohydrate, wherein the pharmaceutical acceptable salt of glycopyrronium is the enantiomerically enriched R,R-form, (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium, wherein the enantiomerically enriched R,R-form has an enantiomeric purity of 90% minimum enantiomeric excess (ee), and wherein the pharmaceutical formulation is a fixed combination as a dry powder.

Basis for this claim is found in the specification as originally filed, and more specifically, on page 3, lines 1-4 and 35-38, page 4, line 1, page 6, lines 7-9, page 7, lines 34-42, and page 10, lines 1-34.

7. Grounds of Rejection to be Reviewed on Appeal

A. Rejection of claims 1, 4, 8-11 and 19 under 35 USC § 103(a)

Whether the identified claims are unpatentable under 35 USC § 103(a) as obvious over Noe et al. (US Patent No. 6,613,795) in view of Wurst et al. (US 2007/0025923).

8. Arguments

A. Rejection of claims 1, 4, 8-11 and 19 under 35 USC § 103(a)

Appellants respectfully submit that the rejection of the identified claims under 35 USC § 103(a) as unpatentable over Noe et al. in view of Wurst et al. is improper and should be reversed.

The state of the law

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under 35 USC § 103 by: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of non-obviousness.

Furthermore, to establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention

does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Also, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would have been obvious to modify the references to produce the present invention. See *Ex parte Clapp*, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the ordinary skilled artisan would have found the claimed invention to have been obvious in light of the reference teachings. *Id.* at 974.

The presently claimed subject matter

Independent claim 1 is directed to "a pharmaceutical formulation consisting of a pharmaceutical acceptable salt of glycopyrronium in combination with ciclesonide, and lactose monohydrate, wherein the pharmaceutical acceptable salt of glycopyrronium is the enantiomerically enriched R,R-form, (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium, wherein the enantiomerically enriched R,R-form has an enantiomeric purity of 90% minimum

enantiomeric excess (ee), and wherein the pharmaceutical formulation is a fixed combination as a dry powder."

No *prima facie* case of obviousness has been properly established

It is submitted that a proper case of *prima facie* obviousness has not been established because Noe et al. fails to teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson.* Further, the Wurst et al. reference is disqualified as prior art under 35 U.S.C. §103(c), and therefore cannot be relied on in any attempt to establish a *prima facie* case of obviousness.

The teachings of Noe et al.

Noe et al. teach enantiomerically pure glycopyrronium with at least 90% enantiomeric excess of the (3R, 2'R) configured enantiomer that can be combined with a pharmaceutically acceptable carrier as a dry powder formulation. However, Noe et al. do not teach or suggest every element of the present subject matter. Nowhere do Noe et al. teach a dry powder formulation ***consisting of*** a pharmaceutical acceptable salt of glycopyrronium ***in combination with ciclesonide***, and lactose monohydrate, as presently claimed. As conceded by the Examiner at page 4 of the Official Action, "Noe et al. fail to disclose ciclesonide."

Thus, Noe et al. does not teach or suggest all the limitations of the claims as required by *In re Wilson*. The cited Wurst et al. reference cannot be relied upon to remedy the deficient teachings of the Noe et al. reference.

The Wurst et al. reference

The Wurst et al. reference is not valid prior art against the present application for purposes of the instant rejection under 35 U.S.C. §103(a). In particular, the Wurst et al. reference is only 35 U.S.C. §102(e) prior art against the present application and falls within the 35 U.S.C. §103 (c)(1) exception.

35 U.S.C. §103(c)(1) states:

> "Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section ***where the subject matter and the claimed invention were, at the time the claimed invention was made***, owned by the same person or ***subject to an obligation of assignment to the same person***." (emphasis added)

The Wurst et al. reference is a US published application which claims priority to provisional U.S. application 60/502,984, filed September 16, 2003. Wurst et al. entered the U.S. national stage from PCT/EP04/52172 filed September 15, 2004 and all §371 (c)(1)(2)(4) requirements were met on March 9, 2006. The §102(e) date for the Wurst et al. reference is the date of the US provisional application – i.e. September 16, 2003. The Wurst et al. reference published February 1, 2007.

The captioned application claims priority to European priority application EP 04004473.7, filed February 27, 2004. Thus, the Wurst et al. reference is only 35 U.S.C. §102(e) prior art against the present application. Further, at the time the claimed subject matter was made, the instant application and the Wurst et al. application were

subject to an obligation of assignment to the same entity – "Altana Pharma AG" of Konstanz, Germany.

Therefore, the Wurst et al. reference clearly falls within the 35 U.S.C. §103(c)(1) exception and does not qualify as prior art against the present application. As such, Wurst et al. cannot be relied on by the Examiner to attempt to establish a *prima facie* case of obviousness.

Accordingly, because the cited Noe et al. reference does not teach or suggest a dry powder formulation ***consisting of*** a pharmaceutical acceptable salt of glycopyrronium ***in combination with ciclesonide***, and lactose monohydrate, as presently claimed, the Noe et al. reference does not establish a *prima facie* case of obviousness.

As such, claims 1, 4, 8-11 and 19 are not obvious under 35 U.S.C. §103(a) and appellants respectfully request that the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 1, 4, 8-11 and 19.

If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 14-0112.

Respectfully submitted,
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Date: January 26, 2011

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9. Claims Appendix

1. (Previously presented) A pharmaceutical formulation consisting of a pharmaceutical acceptable salt of glycopyrronium in combination with ciclesonide, and lactose monohydrate,

wherein the pharmaceutical acceptable salt of glycopyrronium is the enantiomerically enriched R,R-form, (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium,

wherein the enantiomerically enriched R,R-form has an enantiomeric purity of 90% minimum enantiomeric excess (ee), and

wherein the pharmaceutical formulation is a fixed combination as a dry powder.

2. (Canceled).

3. (Canceled).

4. (Previously presented) The formulation according to claim 1, wherein the ciclesonide is selected from the group consisting of [11β,16α-(R)]-16,17-[(Cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregn a-1,4-dien-3,20-dion, [11β,16α(S)]-16,17-[(Cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxoprop-oxy)pregna-1,4-dien3,20-dion, [11β,16α(R,S)]-16,17-[(Cyclohexyl-methylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxoprop-oxy)pregna-1,4-dien3,20-dion,

16α,17- (22R)-Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1,4-dien-3,20-dion, 16α,17-(22S)- Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1,4-dien-3,20-dion and 16α,17- (22R,S)-Cyclohexylmethylendioxy-11β,21-dihydroxy-pregna-1,4-dien-3,20-dion.

5. (Canceled).

6. (Canceled).

7. (Canceled).

8. (Previously presented) The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium is (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide, which substantially does not contain glycopyrronium in the S,S-, S,R- and/or R,S- forms.

9. (Previously presented) The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium and ciclesonide are present in an amount and ratio to be effective for a twice or once daily treatment of a clinical condition in a mammal for which a corticosteroid and/or an anticholinergic agent is indicated.

10. (Previously presented) The formulation according to claim 1, which is suitable for administration by inhalation.

11. (Previously presented) The formulation according to claim 1, which is suitable for nasal administration.

12. (Canceled).

13. (Canceled).

14. (Withdrawn) A method of treatment of a clinical condition in a mammal, for which a corticosteroid and/or an anticholinergic agent is indicated, which comprises administration of a therapeutically effective amount of a pharmaceutical formulation comprising ciclesonide or a pharmaceutical acceptable salt, solvate, or physiologically functional derivative thereof in combination with a pharmaceutical acceptable salt of glycopyrronium, a solvate, or physiologically functional derivative thereof, and a pharmaceutical acceptable carrier and/or one or more excipients.

15. (Withdrawn) The method according to claim 14, wherein the clinical condition is selected from the group consisting of asthma, nocturnal asthma, exercise-induced asthma, chronic obstructive pulmonary diseases (COPD), chronic bronchitis, wheezy bronchitis, emphysema, shortness of breath, respiratory tract infection, upper respiratory tract disease, rhinitis, allergic rhinitis and seasonal rhinitis.

16. (Withdrawn) The method according to claim 15, which comprises a twice daily dosage regimen.

17. (Withdrawn) The method according to claim 15, which comprises a once daily dosage regimen.

18. (Withdrawn) The method according to claim 15, which comprises administration of a combination of a pharmaceutical acceptable salt of glycopyrronium and ciclesonide in the same administration form by inhalation from an inhaler and wherein each actuation provides a dose therapeutically effective for a twice daily dosing regiment or for a once daily dosing regiment.

19. (Previously presented) A dry powder inhalation product comprising a pharmaceutical composition according to claim 1.

10. Evidence Appendix

No information is appended under this section.

11. Related Proceedings Appendix

No information is appended under this section.